



HTAi Patient and Citizen Involvement in HTA Interest Sub-Group (PCISG) E-Bulletin, February 2015

Our vision: Patient and citizen perspectives improve HTA



HTAi 2015, Global Efforts in Knowledge Transfer: HTA to Health Policy and Practice

www.htai2015.org

—organized by the Norwegian Knowledge Centre for the Health Services in collaboration with the HTA agencies from Sweden, Denmark and Finland.

Key Meeting Sub-themes/Plenary Topics Producing HTA

- Knowledge in the 21st century—What, when and how?
- Using the knowledge: Needs of decision makers, clinicians and patients
- International collaboration in knowledge synthesis and transfer: Is it worth the effort?

PCISG Preconference events:

- Sunday 14 June, morning: half-day workshop on 'Supporting patient groups to provide input on patient experiences to inform HTAs through the use of our resources'
- Sunday 14 June, afternoon: half-day meeting and panel discussion on 'What do HTA agencies, policy makers and governments need to convince them to involve patients in HTA processes?'

Registration

Early Bird Deadline: April 1, 2015

Travel grant applications now closed

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The Citizen and Patient Involvement Library in the HTAi Vortal

Steering Committee member Jackie Street has agreed to be responsible for updating the references in the Library. She will working on the update, with Patrice Chalon of the Information Resources ISG, over the next few weeks.

Please check if your references, or references that you use in your work in this area, are there. If not please forward them to us, ideally with the PubMed number.

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Update from the PCISG Working Groups

Patient Charter on Values and Standards: A Group has been put together to work on a Charter for patient groups from the Values and Standards for patient involvement. Our intent is to have a draft for broad consultation by June 2015.
If you know of a well set out Charter please let us know.

HTA Agency Good Practice Examples: the Netherlands has been added.
If you work for an Agency that is not included we would very much appreciate your input as this is a very useful resource.
<http://www.htai.org/interest-sub-groups/patient-and-citizen-involvement.html>

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'The Scottish Medicines Consortium and public attitudes to the provision of medicines for the NHS in Scotland', Scottish Health Council, Healthcare Improvement Scotland report

Following a request from the Patient and Public Involvement Group (PAPIG) of the Scottish Medicines Consortium, we held a series of discussion groups to engage with members of the public about the work of [the Scottish Medicines Consortium and public attitudes to the provision of medicines in the NHS in Scotland](#) .

The purpose of these discussion groups was to:

- explain the role of the Scottish Medicines Consortium in relation to access to medicines in Scotland
- explain how patient and public opinion is brought into consideration in discussions and decisions about medicines and medicine use within the Scottish Medicines Consortium, and
- learn from participants about their understanding of and expectations for the provision of medicines

A total of 94 people participated in 10 discussion groups which took place across Scotland between November 2013 and June 2014.

Richard Norris would be grateful for any feedback on this report

http://www.scottishhealthcouncil.org/about_us/what_we_do/community_engagement/public_attitude_to_medicines.aspx#.VNEFZdKsUk0

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What are the societal values that need to be considered when making decisions about trade-offs between equity and efficiency?

Sarah Garner, lead for the NICE (UK) Citizens Council has sent us this recently produced report (8 to 9 May 2014) <http://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf>

Safeguarding the vulnerable, Justice, Dignity, Value/quality of service, Maximising total benefit, Fairness, Education, Collective responsibility, Humility, Health and welfare for all, Respect, Honesty, Accountability, Quality of life, Realism, Compromise, Respect for the majority/democracy, Individual choice, Being non-judgemental, Independence, Representation/voice, Empathy, Freedom/liberty, Individual rights, Service for all regardless of economics

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EUPATI have a Spring Conference scheduled in Dublin, Ireland:

EUPATI TAKING OFF IN YOUR COUNTRY, an interactive workshop, 22-23 April
Patients and patient organisations that are accepted can register for free.

Eibhlin Mulroe, CEO of IPPOSI (<http://www.ipposi.ie/>):

IPPOSI sat on a panel at the Oireachtas Health Committee hearing on the National Rare Diseases Plan for Ireland, and the videos of this session will be on our website shortly. Deputies and Senators asked specific questions about the resourcing of the National Office for Rare Diseases, and the National Centre for Medical Genetics. Anyone concerned with rare diseases should watch this informative session

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EUPATI, European Patients' Academy on Therapeutic Innovation

For patient advocates in Europe: Become a Patient Expert in Medicines Research and Development

- Interacting with clinical designers and regulatory authorities about new medicines
- Learning with 50 other top patient advocates from around Europe

The course starts in September 2015 and runs for 14 months. Apply here for the 2015 Course before 31 March 2015: <http://www.patientsacademy.eu/index.php/en/edu/guide>

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Measuring and Valuing Health

An interesting, free online course hosted by the UK University of Sheffield (started 16 February 2015) on 'Measuring and Valuing Health', being: <https://www.futurelearn.com/courses/valuing-health>. I recommend that you have a look at the trailer.

FutureLearn is an Open University initiative, offering free courses hosted by an array of academic institutions from the UK and abroad.

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CADTH patient input to Scientific Advice

CADTH has just launched their new Scientific Advice process and they are doing it with meaningful patient involvement. See the form at the following, which summarises the situation.

<http://scientificadvice.cadth.ca/media/templates/SA-Patient-Drug-Information-Form.docx>

Their briefing book for manufacturers asks specifically if they have involved patients in drug development, and to state explicitly if they have not.

Sarah Berglas, Terri O'Grady and Ken Bond have had important roles in this work.

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The Innovative Medicines Initiative funds a range of public-private research projects via funding calls. See its helpful guidance on how to involve patients in applications for research grants and designing and conducting studies.

<http://www.imi.europa.eu/sites/default/files/uploads/documents/Publications/PatientInvolvementCalls3and4.pdf>

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Patient preferences considered for the first time in FDA decision - to approve first-of-kind obesity device:

An obesity preference study to provide the scientific data to quantify the tradeoffs patients were willing to make among the benefits and risks of a weight-loss device or to use this type of information when assessing the benefits and risks of a new technology.

RTI Health Solutions (RTI-HS) partnered with the U.S. Food and Drug Administration (FDA) to conduct a study on patients' preferences which contributed to the Agency's regulatory decision to approve the device. The study estimated the maximum mortality risk patients were willing to accept for a certain amount of weight loss, and the minimum amount of weight loss sufficient to undergo the risks of a weight loss device. FDA [Blog Post \(http://blogs.fda.gov/fdavoices/index.php/2015/01/listening-to-patients-views-on-new-treatments-for-obesity/\)](http://blogs.fda.gov/fdavoices/index.php/2015/01/listening-to-patients-views-on-new-treatments-for-obesity/)

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Additional reading:

Lopes E, Street J, Carter D, Merlin T. Involving patients in health technology funding decisions: stakeholder perspectives on processes used in Australia.

Health Expect. 2015 Feb 21. doi: 10.1111/hex.12356. [Epub ahead of print]

PMID: 25703958

la Cour K, Ledderer L, Hansen HP (2015). "An arena for sharing": Exploring the joint involvement of patients and their relatives in a cancer rehabilitation intervention study. Cancer Nursing. 38;2: E1-E9.

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Rare disease: The Patient - Patient-Centered Outcomes Research. 2015, Volume 8 Number 1

Editorial: Facey K, Hansen HP (2015). The Imperative for Patient-Centred Research to develop Better Quality Services in Rare Diseases. The Patient: Patient-Centered Outcomes Research. 8:1-3.

Some of the other articles in this issue:

- Cees Smit. Personal Reflections of a Patient Representative in an Appraisal Committee
- Durhane Wong-Rieger, William Claxton, Richard Vines, Carmencita Padilla, Kin Ping Tsang & Lucy Hickinbotham. An Asia Pacific Alliance for Rare Diseases
- Devidas Menon, Tania Stafinski, Andrea Dunn & Hilary Short. Involving Patients in Reducing Decision Uncertainties Around Orphan and Ultra-Orphan Drugs: A Rare Opportunity? (Systematic review)
- Jeppesen J, Rahbek J, Gredal O, Hansen HP (2015). How Narrative Journalistic Stories Can Communicate the Individual's Challenges of Daily Living with Amyotrophic Lateral Sclerosis The patient: Patient-Centered Outcomes Research. 8:41-49.
- Aaron S. Kesselheim, Sarah McGraw, Lauren Thompson, Kelly O'Keefe & Joshua J. Gagne. Development and Use of New Therapeutics for Rare Diseases: Views from Patients, Caregivers, and Advocates
- John F. P. Bridges, Victoria Federico Paly, Elizabeth Barker & Dolly Kervitsky. Identifying the Benefits and Risks of Emerging Treatments for Idiopathic Pulmonary Fibrosis: A Qualitative Study
- Nick Dragojlovic, Shirin Rizzardo, Nick Bansback, Craig Mitton, Carlo A. Marra & Larry D. Lynd. Challenges in Measuring the Societal Value of Orphan Drugs: Insights from a Canadian Stated Preference Survey
- Devidas Menon, Tania Stafinski, Andrea Dunn & Durhane Wong-Rieger. Developing a Patient-Directed Policy Framework for Managing Orphan and Ultra-Orphan Drugs Throughout Their Lifecycle

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Surviving Terminal Cancer film premieres in London, New York and online

"Surviving Terminal Cancer" is a documentary following the story of Ben Williams (a glioblastoma survivor who was diagnosed in 1995) and other long term brain tumour survivors. This privately-funded film

premiered in London on February 4th; New York on February 18th, and is now available for free streaming online.

<http://www.survivingterminalcancer.com/>

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New journal now accepting submissions: *Research Involvement and Engagement* <http://www.researchinvolvement.com>

The journal aims to develop the evidence-base underpinning patient and public involvement and engagement in health research. The Editorial Board includes academics, patients, carers and policy-makers, working together.

Research Involvement and Engagement is published by [BioMed Central](#), the leading open access publisher. It is part of the Medical Evidence portfolio, and can benefit from its close relationship with journals such as [Trials](#), [Systematic Reviews](#) and [Journal of Negative Results in BioMedicine](#).

Authors who genuinely cannot afford to pay the article-processing charge are able to request a discretionary waiver, to allow patients, carers and those without institutional funding to submit.

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[Orphanet Journal of Rare Diseases](#) is an [open access](#), online journal that encompasses all aspects of rare diseases and orphan drugs, including rare immunological diseases. The journal publishes high-quality reviews on specific rare diseases, and also considers clinical trial outcome reports and articles on public health issues in the field. We are the official journal of [Orphanet](#) – the global portal for rare diseases and orphan drugs.

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An open letter to PM Modi: invest in lives in Africa, February 2015

Sent to us by **Joshua Wamboga I Executive Director** Uganda Alliance of Patients' Organizations (UAPO)

India's investment strategies should focus on the rights and needs of people — not corporations and foreign governments

Uganda is an East African country, home to 1.6 million people living with HIV. Up to 80% of drugs to Uganda are imports from India, which is well-known as the "pharmacy of the developing world."

Low-cost Indian generics have made life-saving HIV treatment accessible and have presented the possibility of stronger national production capacity through technical support from Indian companies.

Patent monopolies

Apart from HIV, Indian generics have expanded access to game-changing treatment for life threatening diseases such as hepatitis C and treatments for non-communicable diseases. That is why Ugandan health activists are gravely concerned by your recent comments to President Obama, suggesting that India is set to provide stronger intellectual property rights. A decision by your Government to appease Big Pharma could go against the health needs of poor people. It means prices will rise, particularly for newer medicines, where patent monopolies are major barriers to access. It will also damage India's reputation: up to now India has prioritised a people-centred model of investment that has extended a lifeline to millions of people around the world.

An approach to investment that values and supports people, public health, and access to medicines for all as a public good, is innovative, transformative and sets a precedent globally. In Uganda, we are counting on the Indian Government to stand strong — despite threats and misrepresentation of India's pro-public health intellectual property policies. Multinational pharmaceutical companies claim India's rules are not legal and

discourage innovation. Some companies have threatened to withhold investment if India does not extend pharmaceutical monopolies and halt the country's generic industry. India's current policies prioritise life and health over an approach to intellectual property that protects minor changes to medicines. These pro-public health laws have meant India's pharmaceutical industry has been able to flourish — patents are only granted on new medicines or for significant changes on old medicines.

By contrast, the approach by countries such as the US is to grant patent monopolies for every minor change, even when they have no curative benefit. This has resulted in sky-high prices that undermine access. India's approach saves substantial amounts of money by ensuring the costs of medicines are as low as possible. Importantly, there is no evidence that toughening intellectual property rules actually generates more investment by companies — but it is true that such moves cause the cost of healthcare to skyrocket, creating substantial additional burdens — not just in India but across the developing world. Such moves in India will be felt in communities far beyond its borders.

New lessons

We should all learn lessons from the actions of India. It is almost unimaginable that India would sacrifice this position as a leader in extending medicines access. And this could happen if India is not watchful on the policy it adopts, even as it invites US government comments on the draft of India's IP policy.

Mr Prime Minister, the world is watching. Countless lives depend on the actions your Government will take. Listen to our plea: India's investment strategies ought to focus on the rights and needs of people — not corporations and foreign governments. Do not bend to corporate influence, instead, be influenced by the moral imperative — not to cut a lifeline to millions of patients around the world.

Primah Kwagala is a Programme Manager at the Center for Health, Human Rights and Development (CEHURD) based in Kampala, Uganda. Asia Russell is the Executive Director of the Health Global Access Project (Health GAP) and is also based in Kampala.

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Civil Society Demands Government of Uganda Halt Plan to Export Life Saving Health Workers 6/2/15 (Kampala)

A coalition of civil society organizations today criticized a controversial plan by the Government of Uganda to export almost 300 professional health workers to the tiny oil-rich Caribbean nation of Trinidad and Tobago. The plan, which is being challenged in High Court, would result in Uganda—a country suffering from a 'critical' health worker shortage according to the World Health Organisation—being further depleted of midwives, doctors, psychiatrists, and other highly sought-after cadres of health workers. The coalition also reacted for the first time to the filings of the Attorney General in response to the Court case, claiming that the filings reveal a government 'out of touch' with the struggle for access to life saving health services.

Joshua Wamboga | Executive Director

Uganda Alliance of Patients' Organizations (UAPO)

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Janet Wale, Chair HTAi PCISG
E-mail: socrates111@bigpond.com

I am happy to address any questions you may have as a result of this e-Bulletin, and to forward information.



VALUES AND QUALITY STANDARDS FOR PATIENT INVOLVEMENT IN HTA

The HTAi Interest Sub-Group for Patient/Citizen Involvement in Health Technology Assessment (HTA) has developed Values and Quality Standards for patient involvement in HTA via an 18-month research process^[1]. This included an evidence review, nominal group technique with an expert work shop and three-round Delphi process to develop international consensus. The consensus process received input from 150 respondents in 39 countries.

Values for Patient Involvement in HTA

Relevance

Patients have knowledge, perspectives and experiences that are unique and contribute to essential evidence for HTA.

Fairness

Patients have the same rights to contribute to the HTA process as other stakeholders and have access to processes that enable effective engagement.

Equity

Patient involvement in HTA contributes to equity by seeking to understand the diverse needs of patients with a particular health issue, balanced against the requirements of a health system that seeks to distribute resources fairly among all users.

Legitimacy

Patient involvement facilitates those affected by the HTA recommendations/decision to participate in the HTA; contributing to the transparency, accountability and credibility of the decision-making process.

Capacity building

Patient involvement processes address barriers to involving patients in HTA and build capacity for patients and HTA organizations to work together.

Quality Standards for Patient Involvement in HTA

^[1] This research was led by Karen Facey PhD who was partially funded by an unrestricted research grant from Eli Lilly and Company in collaboration with a Research Steering Committee from the HTAi Interest Sub-Group including Professor Helle Ploug Hansen, Moira Howie, David Grainger, Elaine Macphail, Ann Single, Sophie Staniszewska PhD, Sophie Werko PhD, Janet Wale PhD.

General HTA process

1. HTA organizations have a strategy that outlines the processes and responsibilities for those working in HTA and serving on HTA committees to effectively involve patients.
2. HTA organizations designate appropriate resources to ensure and support effective patient involvement in HTA.
3. HTA participants (including researchers, staff, HTA reviewers and committee members) receive training about appropriate involvement of patients and consideration of patients' perspectives throughout the HTA process.
4. Patients and patient organizations are given the opportunity to participate in training to empower them so that they can best contribute to HTA.
5. Patient involvement processes in HTA are regularly reflected on and reviewed, taking account of the experiences of all those involved, with the intent to continuously improve them.

For individual HTAs

6. Proactive communication strategies are used to effectively reach, inform and enable a wide range of patients to participate fully in each HTA.
7. Clear timelines are established for each HTA with advance notice of deadlines to ensure that appropriate input from a wide range of patients can be obtained.
8. For each HTA, HTA organizations identify a staff member whose role is to support patients to contribute effectively to HTA.
9. In each HTA, patients' perspectives and experiences are documented and the influence of patient contributions on conclusions and decisions is reported.
10. Feedback is given to patient organizations who have contributed to an HTA, to share what contributions were most helpful and provide suggestions to assist their future involvement.

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